UNITED STATES DISTRICT COURT
THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

CHIEF JUDGE EDMUND A. SARGUS
Magistrate Judge Kimberly A. Jolson

This document relates to:
Randolph Johnson

Civil Action No. 2:18-cv-1194

ORIGINAL COMPLAINT

Plaintiff files this Complaint pursuant to Case Management Order 2 and is to be bound by the rights, protections, and privileges and obligations of that Order. Plaintiff further states the following:

1. This is a device tort action brought on behalf of the Plaintiff, Randolph Johnson, arising out of the failure of Defendants' hernia mesh product, the Bard PerFix Plug ("PerFix Plug"). As a result, Plaintiff Johnson has suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiff respectfully seeks all damages to which he may be legally entitled.

STATEMENT OF PARTIES

2. Plaintiff is, and was, at all relevant times, a citizen and resident of Arkansas and the United States.

3. Davol, Inc. ("Davol") is incorporated in Delaware and has its principal place of business in Rhode Island. Davol is a medical device company involved in the research, development, testing, manufacture, production, marketing, promotion and/or sale of medical

devices, including an inguinal dart-shaped hernia mesh composed of polypropylene and known as the PerFix Plug.

4. C.R. Bard, Inc. ("Bard") is incorporated and based in New Jersey. Bard is a multinational marketer, promoter, seller, producer, manufacturer, and developer of medical devices. Bard controls the largest share of the hernia mesh market. It is the corporate parent/stockholder of Davol and participates in the manufacture and distribution of the PerFix Plug. Bard also manufactures and supplies Davol with material that forms part of the PerFix Plug.

5. Bard was at all relevant times responsible for the actions of Davol, and exercised control over Davol's functions specific to the oversight of and compliance with applicable safety standards relating to and including PerFix Plug sold in the United States. In such capacity, Bard committed or allowed to be committed tortious and wrongful acts, including the violation of numerous safety standards relating to device manufacturing, quality assurance/control, and conformance with design and manufacturing specifications. Bard's misfeasance and malfeasance caused Plaintiff to suffer injury and damages.

6. Defendants are individually, jointly and severally liable to Plaintiff for damages suffered by Plaintiff arising from their design, manufacture, marketing, labeling, distribution, sale and placement of the defective PerFix Plug at issue in this suit. All acts were effectuated directly and indirectly through Defendant's respective agents, servants, employees and/or owners, acting within the course and scope of their representative agencies, services, employments and/or ownership.

7. Defendants are vicariously liable for the acts and/or omissions of their employees and/or agents, who were at all relevant times acting on Defendants' behalf and within the scope of their employment or agency with Defendants.

VENUE AND JURISDICTION

8. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) based on complete diversity of citizenship between Plaintiff and all Defendants. The amount in controversy exceeds $75,000.

9. Venue is proper in the District of Arkansas, Western District, pursuant to 28 U.S.C. § 1391 because the events or omissions giving rise to Plaintiff's claims occurred in that district.

10. Defendants continue to conduct substantial business in the above-referenced district, distribute Bard Hernia Mesh in that district, and made material omissions and misrepresentations and breaches of warranties in that district, so as to subject them to *in personam* jurisdiction in that district.

FACTS COMMON TO ALL COUNTS

11. On or about October 26, 2009, Plaintiff Johnson underwent right inguinal hernia repair by Dr. Douglas L. Friesen, MD at Mercy Hospital Northwest in Rogers, Arkansas. A medium PerFix Plug, Ref. No. 0112760, Lot No. HUTF585 was implanted in Plaintiff during this repair.

12. Defendants manufactured, sold, and/or distributed the PerFix Plug to Plaintiff, through Plaintiff's doctors, to be used for treatment of hernia repair.

13. On or about October 6, 2015, Plaintiff Johnson underwent explant surgery of the PerFix Plug by Dr. Ronald Mullis at Fayetteville Veterans Administration Hospital in Fayetteville, Arkansas.

14. Plaintiff Johnson continues to experience complications related to the PerFix Plug. He will likely require additional surgeries to repair the damage from Defendants' product.

15. Defendants' PerFix Plug is a three-dimensional mesh product containing layers of polypropylene with a separate pre-shaped onlay polypropylene patch. Defendants market it as a mesh to be used in repairing hernias.

16. Defendants' PerFix Plug product contains several layers of polypropylene mesh. Despite Defendants' claims that this material is inert, a substantial body of scientific evidence shows that the mesh material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving the product. This immune response promotes degradation and contracture of the polypropylene mesh, as well as the surrounding tissue, and can contribute to the formation of severe adverse reactions to the mesh.

17. Upon information and belief, Defendants' numerous suppliers of various forms of polypropylene cautioned all users in their United States Material Safety Data Sheet that the polypropylene was not to be used for medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

18. Defendants failed to warn or notify doctors, regulatory agencies, and consumers of the severe and life-threatening risks associated with polypropylene.

19. PerFix Plug contains the following components:

A. several layers of polypropylene constructed as a fluted outer layer with multiple inner layers; and

B. one layer of pre-shaped polypropylene mesh with the option to be implanted as an onlay over the plug once implanted.

20. Defendants' PerFix Plug can contract up to 90% post-implantation.

21. In 2015, a study compared the recurrence rates for plug-and-patch hernia repair with standard flat mesh hernia repair utilizing the "Lichtenstein technique." The plug-and-patch had a recurrence rate of 9.9% compared to 5.6% for the standard flat mesh.[1]

22. In 2018, the HerniaSurge Group published *International Guidelines for Groin Hernia Management*. The Guidelines were endorsed by the European Hernia Society, Americas Hernia Society, Asia Pacific Hernia Society, Afro Middle East Hernia Society, Australasian Hernia Society, International Endo Hernia Society, and European Associated for Endoscopic Surgery and Other Interventional Techniques. The HerniaSurge Group's Guidelines note the following: "The incidence of erosion seems higher with plug versus flat mesh. It is suggested not to use plug repair techniques."

23. Defendants were responsible for the research, design, development, testing, manufacture, production, marketing, promotion, distribution and sale of PerFix Plug, including providing the warnings and instructions concerning the product.

24. Among the intended purposes for which Defendants designed, manufactured and sold PerFix Plug was use by surgeons for hernia repair surgeries. That is the purpose for which the PerFix Plug was implanted in Plaintiff.

25. Defendants represented to Plaintiff and Plaintiff's physicians that the PerFix Plug was a safe and effective product for hernia repair.

ESTOPPEL AND TOLLING OF STATUTE OF LIMITATIONS

26. Plaintiff incorporates the allegations in all prior paragraphs.

[1] Nienhuijs, S. and Rosman, C., *Long-term Outcome After Randomizing Prolene Hernia System, Mesh Plug Repair and Lichtenstein for Inguinal Hernia Repair*. Hernia, 19, pp. 77 – 81 (2015).

27. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

28. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating his injury, the cause of the injury, and the tortious nature of the wrongdoing that caused the injury.

29. Despite diligent investigation by Plaintiff into the cause of his injuries, including consultations with Plaintiff's medical providers, the nature of the injuries and damages, and their relationship to the PerFix Plug was not discovered, and through reasonable care and diligence could not have been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, the action was filed well within the applicable statutory limitations period.

30. The running of the statute of limitations is tolled due to equitable tolling. Defendants are estopped from asserting a limitations defense due to their fraudulent concealment, through misrepresentations and omissions, from Plaintiff and Plaintiff's physicians of the true risks associated with the PerFix Plug. As a result of Defendants' fraudulent concealment, Plaintiff and his physicians were unaware, and could not have known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks alleged in this Complaint, and that those risks were the direct and proximate result of Defendants' wrongful acts and omissions.

COUNT I: STRICT LIABILITY – MANUFACTURING DEFECT

31. Plaintiff Johnson incorporates by reference the allegations in all prior paragraphs.

32. Defendants expected and intended the PerFix Plug to reach users such as Plaintiff in the condition in which the product was sold.

33. The implantation of PerFix Plug in Plaintiff's body was medically reasonable and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

34. The PerFix Plug was defectively manufactured when it was implanted in Plaintiff's body.

35. Defendants' poor-quality control and general non-compliance resulted in the non-conformance of the PerFix Plug implanted in Plaintiff. The implanted PerFix Plug did not conform to Defendants' intended manufacturing and design specifications.

36. Upon information and belief, Defendants utilized substandard and adulterated polypropylene in the PerFix Plug, which deviated from Defendants' material and supply specifications.

37. As a direct and proximate result of Defendants' defective manufacture of the PerFix Plug, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

38. Plaintiff Johnson incorporates by reference the allegations in all prior paragraphs.

39. Defendants' PerFix Plug was defectively designed and/or manufactured and was not reasonably safe for its intended use in hernia repair. The risks of the design outweighed any potential benefits associated with the design. As a result of the defective design and/or manufacture of the PerFix Plug, there was an unreasonable risk of severe adverse reactions to the mesh or mesh components including: chronic pain; recurrence of hernia; foreign body response; rejection; infection; scarification; improper wound healing; excessive and chronic inflammation;

allergic reaction; adhesions to internal organs; erosion; abscess; fistula formation; granulomatous response; seroma formation; nerve damage; tissue damage and/or death; and other complications.

40. The PerFix Plug includes a tapered design, which promotes mesh migration in the direction of the taper.

41. The three-dimensional design of the PerFix Plug promotes mesh contracture or mesh "wadding," "balling," or "knuckling" up.

42. Mesh porosity impacts tissue ingrowth and the inflammatory response. Large-pore meshes have fewer complications than small-pore meshes. A pore size greater than 1.5 mm defines "large-pore-size." Complications continue to decrease as mesh pore size increases beyond 1.5 mm. A small-pore-size decreases tissue incorporation increases inflammation, and results in a fibrotic reaction. The PerFix Plug has a mesh pore size of less than 0.5 mm.

43. Large-pore flat meshes have a lower risk of mesh-related complications compared to small-pore three-dimensional meshes like Defendants' PerFix Plug.

44. Shrinkage and stiffness of flexible meshes is affected by scar tissue. The PerFix Plug has smaller inter-filament distances and pores, which increases the risk of bridging by scar tissue.

45. Plugs, when compared with flat meshes, have a higher risk of extensive fibrosis and are more likely to stimulate an intense inflammatory reaction, thereby resulting in nonconforming biomechanical properties.

46. Hernia repair with the PerFix Plug necessitates entering both the anterior and posterior compartments, which is not necessary when repairing a hernia with a standard flat mesh. Entering both the anterior and posterior compartments increases scarring, making a subsequent repair for hernia recurrence more difficult.

47. The PerFix Plug has multiple layers of polypropylene, increasing the mesh surface area and foreign body load, which in turn increases the inflammatory and foreign body response.

48. The polypropylene weave of the PerFix Plug produces very small interstices that allow bacteria to enter and hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing slime (biofilm) that further serves to protect them from destruction by white blood cells and macrophages.

49. Observation of mesh under a scanning electron microscope reveals that very small interstices exists between the PerFix Plug mesh fibrils, which are too small for a macrophage to enter to destroy incubating bacteria. Some bacteria are capable of degrading polypropylene.

50. These manufacturing and design defects associated with the PerFix Plug were directly and proximately related to the injuries Plaintiff Johnson suffered.

51. Neither Plaintiff nor Plaintiff's implanting physician was adequately warned or informed by Defendants of the defective and dangerous nature of PerFix Plug. Moreover, neither Plaintiff nor his implanting physician was adequately warned or informed by Defendants of the risks associated with the PerFix Plug.

52. The PerFix Plug implanted in Plaintiff Johnson failed to reasonably perform as intended. The PerFix Plug caused serious injury and had to be surgically removed via invasive surgery.

53. As described above, there was an unreasonable risk that the PerFix Plug, which was defectively designed, would not perform safely and effectively for the purposes for which it was intended. Defendants failed to design against such dangers and failed to provide adequate warnings and instructions concerning these risks.

54. Defendants expected and intended the PerFix Plug to reach users such as Plaintiff in the condition in which the PerFix Plug was sold.

55. The implantation of the PerFix Plug in Plaintiff's body was medically reasonable and was a type of use that Defendants intended and foresaw when they designed, manufactured and sold the product.

56. The risks of the PerFix Plug significantly outweigh any benefits that Defendants contend could be associated with it. The dart-like design—which is not used in any other hernia mesh product sold in the United States—promotes mesh migration and incites an intense inflammatory response, leading to encapsulation, deformation, scarification and contraction, erosion, rejection and further migration.

57. The polypropylene mesh utilized to manufacture the PerFix Plug was in and of itself dangerous and defective, particularly when used in the manner intended by Defendants in the PerFix Plug. Upon information and belief, the particular polypropylene material used in the PerFix Plug was substandard, adulterated and non-medical grade, and was unreasonably subject to oxidative degradation within the body. When implanted as intended, polypropylene mesh is unreasonably susceptible to adhesion formation, nerve entrapment, spermatic cord obliteration, organ perforation or erosion, fistula formation and bowel strangulation or hernia incarceration, and other injuries.

58. The appropriate treatment for complications associated with the PerFix Plug involves additional invasive surgery to remove the mesh from the body, thus eliminating any purported benefit that the mesh was intended to provide to a patient.

59. When the PerFix Plug was implanted in Plaintiff, there were safer feasible alternative designs for hernia mesh products.

60. The PerFix Plug product cost significantly more than competitive products because of its unique dart shape—even though the dart shape provided no benefit to consumers and increased the risks to patients implanted with these devices.

61. The PerFix Plug implanted in Plaintiff Johnson failed to reasonably perform as intended. It had to be surgically removed, necessitating further invasive surgery to repair the very issue that the product was intended to repair, and thus providing no benefit to him.

62. As a direct and proximate result of the defective and unreasonably dangerous condition of the product, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT III: STRICT LIABILITY – FAILURE TO WARN

63. Plaintiff incorporates by reference the allegations in all prior paragraphs.

64. When the PerFix Plug was implanted in Plaintiff's body, the warnings and instructions Defendants provided were inadequate and defective. As described above, there was an unreasonable risk that the product would not perform safely and effectively for the purposes for which it was intended, and Defendants failed to design and/or manufacture against such dangers and failed to provide adequate warnings and instructions concerning these risks.

65. Defendants expected and intended the PerFix Plug product to reach users such as Plaintiff Johnson in the condition in which the product was sold.

66. Plaintiff and his physicians were unaware of the defects and dangers of the PerFix Plug, and were unaware of the frequency, severity and duration of the risks associated with the product.

67. The Instructions for Use Defendants provided with the PerFix Plug are silent on the fact of the PerFix Plug's propensity to migrate post-implantation in the direction of the taper.

Defendants provided no warning to physicians about the risks or increased risks specifically associated with the unique dart-like design of the PerFix Plug.

68. The Instructions for Use for the PerFix Plug also failed to adequately warn Plaintiff's physicians of numerous risks that Defendants knew or should have known were associated with the PerFix Plug, including: risks of the product's immunologic response, pain, encapsulation, rejection, migration, scarification, contraction, adhesion to internal structures or organs, erosion and migration through adjacent tissue and viscera, bowel obstruction, or hernia incarceration or strangulation.

69. Defendants failed to adequately warn implanting surgeons of the significant risk of complications associated with mesh migration if the PerFix Plug is implanted in the abdomen to repair a ventral hernia.

70. Defendants failed as well to adequately warn Plaintiff or Plaintiff's physicians about the necessity for invasive surgical intervention in the event of complications with the PerFix Plug or train the physicians on the proper treatment of such complications when they occurred.

71. Defendants failed to adequately warn Plaintiff or his physicians that: the surgical removal of the PerFix Plug in the event of complications would leave the hernia unrepaired; the resulting hernia would be much larger than the original; and further, more complicated medical treatment to attempt to repair the same hernia would be necessary.

72. Defendants represented to physicians, including Plaintiff's physician, that the tapered design would prevent or reduce recurrences and pain. They expressly intended for the PerFix Plug to be implanted near numerous large nerves and organs and marketed and promoted the PerFix Plug for that purpose. Defendants failed to warn physicians that the PerFix Plug would contract over time, increasing the rates of recurrence and the ability of the PerFix Plug to migrate.

73. With respect to the complications listed in their warnings, Defendants provided no information or warning regarding the frequency, severity and duration of those complications, although the complications associated with the PerFix Plug were more frequent, more severe and longer lasting than those in safer feasible alternative hernia repair treatments.

74. If Plaintiff and/or Plaintiff's physicians had been properly warned of the defects and dangers of the PerFix Plug, and of the frequency, severity and duration of the risks associated with the product, Plaintiff would not have consented to allow the PerFix Plug to be implanted, and Plaintiff's physicians would not have implanted the product in Plaintiff.

75. As a direct and proximate result of the inadequate and defective warnings and instructions, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT IV: NEGLIGENCE

76. Plaintiff incorporates by reference the allegations in all prior Paragraphs.

77. Although Defendants had a duty to use reasonable care in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for the PerFix Plug, they failed to do so.

78. Defendants knew, or in the exercise of reasonable care should have known, that the PerFix Plug was defectively and unreasonably designed and/or manufactured and was unreasonably dangerous and likely to injure patients in whom the product was implanted. Defendants knew or should have known that Plaintiff and Plaintiff's physicians were unaware of the dangers and defects inherent in the PerFix Plug.

79. Defendants knew or should have known that the Material Data Safety Sheet for the polypropylene used to manufacture their PerFix Plug prohibited permanently implanting the polypropylene into the human body.

80. Defendants utilized non-medical grade polypropylene.

81. Defendants knew or should have known that polypropylene is not inert and would degrade, flake, chip, and disperse throughout the body once implanted.

82. Defendants knew or should have known that polypropylene incites a severe inflammatory response once implanted and continues to incite a severe inflammatory response indefinitely or until removed.

83. Defendants knew or should have known that every piece of polypropylene that flakes off and migrates throughout the body also incites its own chronic inflammatory response wherever it embeds.

84. Defendants knew or should have known that the tapered design of the PerFix Plug would promote mesh migration.

85. Defendants knew or should have known of the significant risk of complications if the PerFix Plug is implanted into the abdomen to repair a ventral hernia. Nonetheless, Defendants marketed the PerFix Plug off-label as being safe and effective for ventral and abdominal incisional hernia repair.

86. Defendants knew or should have known that small pore size and multiple layers of the PerFix Plug would increase mesh surface area and foreign body load, which in turn would increase the inflammatory and foreign body response.

87. As a direct and proximate result of Defendants' negligence in designing, testing, inspecting, manufacturing, packaging, labeling, marketing, distributing, and preparing written instructions and warnings for PerFix Plug, Plaintiff suffered injuries and damages as summarized in this Complaint.

COUNT V: BREACH OF IMPLIED WARRANTY

88. Plaintiff incorporates by reference the allegations in all prior paragraphs.

89. At all material times, Defendants manufactured, marketed, sold, distributed and otherwise placed in to the stream of commerce the PerFix Plug.

90. At all material times, Defendants intended for their product to be implanted for the purposes and in the manner that Plaintiff and his implanting physician in fact used it; and Defendants impliedly warranted that the product and its component parts were of merchantable quality, safe and fit for such use, and adequately tested.

91. Defendants were aware that consumers, including Plaintiff and his physician, would implant their product as directed by the Instructions for Use. Therefore, Plaintiff was a foreseeable user of Defendants' PerFix Plug.

92. Defendants' PerFix Plug was expected to reach, and did in fact reach consumers, including Plaintiff and his physician, without substantial change in the condition in which it was manufactured and sold by Defendants.

93. Defendants breached various implied warranties with respect to PerFix Plug, including the following:

A. Defendants represented to Plaintiff and his physician and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that their product was save. But at the same time they fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the product;

B. Defendants represented to Plaintiff and his physician and healthcare providers that their product was safe and/or safer than other alternative procedures and devices. But at the same time they fraudulently concealed information demonstrating that the product was not safer than alternatives available on the market; and

C. Defendants represented to Plaintiff and his physician and healthcare providers that their product was more efficacious than alternative procedures and/or devices. But at the same time they fraudulently concealed information regarding the true efficacy of the PerFix Plug.

94. In reliance upon Defendants' implied warranties, Plaintiff, individually, and/or by and through his physician, used the PerFix Plug as prescribed, and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

95. Defendants breached their implied warranties to Plaintiff in that their product was not of merchantable quality, nor was it safe and fit for its intended use or adequately tested.

96. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiff was caused to suffer severe personal injuries, pain and suffering, severe emotional distress, financial or economic loss, including obligations for medical services and expenses, impairment of personal relationships, and other damages.

COUNT VI: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

97. Plaintiff incorporates by reference the allegations in all prior paragraphs.

98. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the PerFix Plug to Plaintiff.

99. Defendants carelessly and negligently concealed the harmful effects of their product from Plaintiff, individually and/or Plaintiff's physician, on multiple occasions. They continue to do so to this day.

100. Defendants carelessly and negligently misrepresented the quality, safety and efficacy of the PerFix Plug to Plaintiff, individually and/or Plaintiff's physician, on multiple occasions. They continue to do so to this day.

101. Plaintiff was directly impacted by Defendants' carelessness and negligence, in that he has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of the decision to purchase the PerFix Plug sold and distributed by Defendants.

102. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the PerFix Plug to Plaintiff, individually and/or Plaintiff's physician, after Plaintiff sustained emotional distress, severe physical injuries, and economic loss.

103. Defendants continued to carelessly and negligently misrepresent the quality, safety, efficacy, dangers and contraindications of the PerFix Plug to Plaintiff, individually and/or Plaintiff's physician, knowing that doing so would cause him to suffer additional and continued emotional distress, severe physical injuries, and economic loss.

104. As a proximate result of the Defendants' acts or omissions, Plaintiff has been injured, sustained severe and permanent pain, suffering, anxiety, depression, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

COUNT VII: FRAUDULENT CONCEALMENT

105. Plaintiff incorporates by reference the allegations in all prior paragraphs.

106. At all material times, Defendants knew or should have known that the PerFix Plug caused large numbers of complications. Moreover, they also knew or should have known the following: the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices; the safety and efficacy of its PerFix Plug had not been proven with respect to, among other things, the product, its components, its performance, and its method of insertion; the PerFix Plug was not safe and effective. But Defendants continued to represent that the PerFix Plug was safe and effective.

107. Despite what Defendants knew or should have known about the lack of safety and efficacy of the PerFix Plug, they failed to disclose this information to Plaintiff Johnson, to Plaintiff's physicians, and to the public at large.

108. At all material times, Defendants had the duty and obligation to disclose to Plaintiff and Plaintiff's physicians the true facts concerning the PerFix Plug: that it was dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and the likelihood of its causing serious consequences to users, including permanent and debilitating injuries. Defendants concealed these material facts before Plaintiff was implanted with their product.

109. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the PerFix Plug because:

A. Defendants were in a superior position to know the true quality, safety, and efficacy of the PerFix Plug;

B. Defendants knowingly made false claims in documents and marketing materials about the safety and quality of the PerFix Plug; and

C. Defendants fraudulently and affirmatively concealed the defective nature of the PerFix Plug from Plaintiff.

110. The facts concealed and/or not disclosed by Defendants to Plaintiff and his physician were material facts that a reasonable person would have considered to be important in deciding whether to purchase and/or use the PerFix Plug.

111. At all material times, Defendants willfully, intentionally, and maliciously concealed facts as set forth above from Plaintiff and his physician, with the intent to defraud.

112. Defendants intentionally concealed and/or failed to disclose the true defective nature of the PerFix Plug so that Plaintiff would request and purchase the product, and his healthcare providers would dispense, prescribe, and recommend the PerFix Plug; and Plaintiff justifiably acted or relied upon the concealed and/or non-disclosed facts to his detriment.

113. At all material times, neither Plaintiff nor Plaintiff's physician was aware of the facts set forth above. Had they been aware of the facts, they would not have acted as they did, *i.e.*, would not have reasonably relied upon the representations of safety and efficacy and utilized the PerFix Plug in their treatment. Defendants' failure to disclose this information was a substantial factor in Plaintiff's physicians selecting Defendants' PerFix Plug. The failure to disclose also resulted in the provision of incorrect and incomplete information to Plaintiff, as a patient.

114. As a direct and proximate result of Defendants' conduct, Plaintiff was injured.

COUNT VIII: NEGLIGENT MISREPRESENTATION

115. Plaintiff incorporates by reference the allegations in all prior paragraphs.

116. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the PerFix Plug had not been adequately tested and found to be a safe and effective treatment. Defendants' representations were in fact false.

117. Defendants failed to exercise ordinary care in the representations concerning the PerFix Plug while they were involved in its manufacture, sale, testing, quality assurance, quality

control, and distribution in interstate commerce, because Defendants negligently misrepresented or concealed the PerFix Plug's high risk of unreasonable and dangerous adverse side effects.

118. Defendants breached their duty in representing to Plaintiff, Plaintiff's physicians, and the medical community, that the PerFix Plug had no serious side effects different from those of other similar products and/or procedures.

119. As a foreseeable, direct, and proximate result of Defendants' negligent misrepresentation, they knew or should have known that the PerFix Plug had been insufficiently tested, or had not been tested at all. As well, they knew or should have known that the product lacked adequate and accurate warnings, creating a high risk—or higher than acceptable or reported and represented risk—of adverse side effects. Those included pain, graft rejection, graft migration, organ damage, complex seroma, fistula, sinus tract formation, delayed wound closure, infection, sepsis, and death.

120. As a direct and proximate result of Defendants' acts and omissions, Plaintiff Johnson has been injured and sustained severe pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, economic damages.

PUNITIVE DAMAGES

121. Plaintiff incorporates by reference the allegations in all prior paragraphs.

122. Defendants failed to adequately test and study the PerFix Plug to determine and ensure that the product was safe and effective before releasing the product for sale for permanent human implantation; and Defendants continued to manufacture and sell the product after having obtained knowledge and information that it was defective and unreasonably unsafe.

123. Although Defendants have other hernia repair mesh devices that do not present the same risks as the PerFix Plug, they developed, designed and sold the PerFix Plug, and continue to

do so, because the PerFix Plug has a significantly higher profit margin than other hernia repair products. Defendants were aware of the probable consequences of implantation of the dangerous and defective PerFix Plug, including the risk of failure and serious injury, such as suffered by Plaintiff.

124. At all material times, Defendants knew or should have known that the PerFix Plug was inherently more dangerous with respect to the following risks: migration, foreign body response, allergic reactions, rejection, infection, failure, erosion, pain and suffering, organ perforation, dense adhesions, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the product's use, as well as other permanent and lasting severe and personal injuries.

125. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the PerFix Plug, thus depriving Plaintiff and his implanting physicians of vitally necessary information necessary to make a fully informed decision about whether to use the product.

126. At all material times, Defendants knew and recklessly and/or intentionally disregarded the fact that the PerFix Plug can cause debilitating and potentially life-threatening side effects with greater frequency than safer alternative methods, products, procedures, and/or treatment. But they recklessly failed to advise the medical community and the general public, including Plaintiff, of the risks and side effects.

127. At all material times, Defendants intentionally misstated and misrepresented data, and continue to misrepresent data, so as to minimize the perceived risk of injuries and the rate of complications associated with PerFix Plug.

128. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true and defective nature of the PerFix Plug's increased risk of side effects and serious complications, Defendants continue to aggressively market the product to the medical community and to consumers without disclosing the true risk of such complications.

129. When Plaintiff Johnson was implanted with the PerFix Plug and since then, Defendants have known that the PerFix Plug was defective and unreasonably dangerous. Nonetheless, they have continued to manufacture, produce, assemble, market, distribute, and sell the product so as to maximize sales and profits at the expense of the health and safety of the public, in a conscious, reckless and/or intentional disregard of the likely and foreseeable harm caused by the PerFix Plug to the public, including Plaintiff.

130. At all material times, Defendants have concealed and/or failed to disclose to the public the serious risks and the potential complications associated with the PerFix Plug, to ensure continued and increased sales and profits, to the detriment of the public, including Plaintiff.

131. Defendants' acts and omissions are of such character and nature so as to entitle Plaintiff to an award of punitive damages in accordance with applicable statutory and common law. Defendants' conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care, which raise the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants, individually, jointly, and severally; and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

Plaintiff Johnson demands judgment against Defendants, individually, jointly and severally, and prays for the following relief in accordance with applicable law and equity:

i. Compensatory damages to Plaintiff for past, present, and future damages, including but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;

ii. restitution and disgorgement of profits;

iii. punitive damages;

iv. reasonable attorneys' fees as provided by law;

v. costs of these proceedings, including past and future costs of suit;

vi. all ascertainable economic damages;

vii. prejudgment interest on all damages as allowed by law; and

viii. such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff Johnson hereby demands a trial by jury on all issues so triable.

Date: October 5, 2018

Respectfully submitted,

/s/ *Sarah A. Wolter*
Sarah A. Wolter
Colorado Bar No. 47599
Sarah.wolter@andruswagstaff.com
ANDRUS WAGSTAFF, PC.
7171 W. Alaska Drive
Lakewood, CO 80226
Telephone (303) 376-6360

Attorneys for Plaintiff